102d Congress
1st Session

COMMITTEE PRINT

S. PRT.
102-50

THE DRUG MANUFACTURING INDUSTRY: A PRESCRIPTION FOR PROFITS

STAFF REPORT

OF THE

SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE

SEPTEMBER 1991

Serial No. 102-F

This document has been printed for information purposes. It does not represent either findings or recommendations formally adopted by this committee.

U.S. GOVERNMENT PRINTING OFFICE

46-236 WASHINGTON : 1991

For sale by the U.S. Government Printing Office
Superintendent of Documents, Mail Stop: SSOP, Washington, DC 20402-9328
ISBN 0-16-035654-7

S142-10.

SPECIAL COMMITTEE ON AGING

DAVID PRYOR, Arkansas, *Chairman*

JOHN GLENN, Ohio	WILLIAM S. COHEN, Maine
BILL BRADLEY, New Jersey	LARRY PRESSLER, South Dakota
QUENTIN N. BURDICK, North Dakota	CHARLES E. GRASSLEY, Iowa
J. BENNETT JOHNSTON, Louisiana	ALAN K. SIMPSON, Wyoming
JOHN B. BREAUX, Louisiana	JAMES M. JEFFORDS, Vermont
RICHARD SHELBY, Alabama	JOHN McCAIN, Arizona
HARRY REID, Nevada	DAVE DURENBERGER, Minnesota
BOB GRAHAM, Florida	LARRY CRAIG, Idaho
HERBERT KOHL, Wisconsin	CONRAD BURNS, Montana
TERRY SANFORD, North Carolina	ARLEN SPECTER, Pennsylvania

PORTIA PORTER MITTELMAN, *Staff Director*
CHRISTOPHER C. JENNINGS, *Deputy Staff Director*
MARY BERRY GERWIN, *Minority Staff Director/Chief Counsel*

PREFACE

For years, consumers and their representatives inside and outside the Congress have expressed great frustration with unrelenting prescription drug price increases. During the 1980's, while the general inflation rate rose 58 percent, the prescription drug inflation rate increased a staggering 152 percent. Since most elderly do not have the benefit of outpatient prescription drug coverage, drug prices represent the highest out-of-pocket medical expense for three out of four elderly. Although particularly taxing for older Americans, there is no question that prescription drug prices represent an onerous burden for Americans of all ages.

It was the hope of many in the Congress that the 1990 enactment of a Medicaid drug rebate law, which will provide modest cost relief to the program that serves the sickest and poorest of our poor, coupled with the scrutiny given to drug prices over the last few years by this and other Congressional Committees, would send a strong message that skyrocketing price increases would no longer be tolerated. Unfortunately, the message is apparently falling on deaf ears within most of the drug manufacturing industry and, as this report indicates, prices are increasing this year at a rate that actually exceeds the unprecedented inflation rates of the 1980's.

Noting the continuing and extremely disturbing price inflation trend, I felt it time to undertake a substantive, up-to-date review of the drug manufacturing industry. What I found startled and disappointed even those of us who have worked on this issue for years. Key findings include:

- During the first 6 months of this year, the overall annualized general inflation rate was 3.3 percent, while the annualized prescription drug inflation rate was a staggering 11.2 percent. Even more distressing, prescription drug price inflation increased 1.3 percent in August 1991, which was six and one-half times the increase in the general inflation rate and was the largest monthly increase for prescription drugs in the last 8 months.

- If current inflation trends continue, an average $20 prescription purchased in 1980 will increase by 600 percent to $120.88 by the turn of the century, whereas it would cost only $49.72 in the year 2000 if the drug increased at the general inflation rate.

- At a time when Americans are scrimping and saving to afford their medications, the drug industry's annual average 15.5 percent profit margin more than triples the 4.6 percent profit margin of the average Fortune 500 company.

● According to a 1991 Department of Health and Human Services Office of Inspector General's report, the average American pays 62 percent more for prescription drugs than the average Canadian citizen and 54 percent more than the average European citizen.

● According to the pharmaceutical industry's own data, drug manufacturers will spend $1 billion more on marketing and advertising than it will on research. Some of these promotional activities paid for by American consumers include all-expense paid "educational symposia" for physicians and their spouses to plush resorts, as well as providing financial incentives to physicians for prescribing certain amounts of medications.

● Beyond underwriting excessive price increases, unmatched profits, multi-billion-dollar marketing campaigns, and hundreds of millions of dollars in research and development tax credits, Americans are also bestowing upon the industry an additional annual $2 billion non-research and development oriented tax credit. Further, there is some evidence to suggest that this tax credit encourages drug companies to close U.S.-based plants, fire workers, and relocate to places such as Puerto Rico. Moreover, by returning to the drug industry $57,761 (264 percent) more in tax credits per employee than the manufacturers are paying in wages (on average $21,180), the Section 936 Tax Credit is an incredibly inefficient and expensive way to create jobs. Amazingly, at a time when Americans are paying the highest prescription drug prices in the world, our taxpayers are effectively reducing—through the Section 936 Tax Credit—the effective tax rate of the drug industry by 9 percent.

Although it is my hope that this report and the public attention given to it will convince the industry that the time for positive, responsive, and constructive change is now, it has become clear that serious legislative interventions may well be the only way to command the drug industry's attention. It is for this reason that the report includes specific policy options for congressional consideration. I hope the following findings and policy option recommendations will make a positive contribution toward assuring that all Americans receive a much better return on their multi-billion dollar investment on prescription drugs.

Sincerely,

DAVID PRYOR,
Chairman.

CONTENTS

	Page
Preface	III
Section I—Prescription Drug Price Inflation	1
Section II—Pharmaceutical Industry's Profitability	3
Section III—Pharmaceutical Industry's Marketing Excesses	4
Section IV—United States Drug Prices vs. Other Industrialized Nations	6
Part 1—Specific Comparisons of Drug Prices Between the United States, Canada, and Europe	6
Part 2—Canada: Case Example of How a Drug Price Review Board Contains Drug Costs	7
Section V—Drug Industry's Billion Dollar Non-Research Oriented Tax Break	10
Section VI—High Drug Prices Produce Few Breakthrough Drugs	13
Conclusion: Policy Options	15

APPENDIX

CHARTS

1. Prescription Drug Price Inflation Sharply Outpaces Medical Inflation	18
2. Prescription Drug Increases Outpace Inflation, July 1980–July 1990	19
3. Prescription Drug Inflation, 1991—1st Half	20
4. A $20 Drug Increases 604 Percent to $120 by Year 2000	21
5. Drug Company Profits: 1990 (Profits as a Percentage of Sales)	22
6. Individual Drug Company Profits: 1990 (Profits as a Percentage of Sales)	22
7. Profitability of the Pharmaceutical Industry 1990: Return on Sales, Return on Assets, Return on Stock Equity	23
8. Drug Manufacturers 1991 Research vs. Marketing Expenditures: As a Percentage of Sales	24
9. Drug Manufacturers 1991 Research vs. Marketing Expenditures: Percentage Increase from Last Year	25
10. International Drug Price Comparison	26
11. Canadian Prescription Drug Price Inflation Decreases Between 1983–1990	27
12. Average Drug Industry Possessions Tax Credit Per Employee Almost Triples Actual Salary Paid	28
13. Drug Industry Possessions Tax Credit Per Employee Far Exceeds Other Industries' Credits	29

TABLES

1. United States versus Canadian prescription drug prices: Prescription products commonly used in the United States and their price variances, 1st quarter 1989	30
2. United States versus Canadian prescription drug prices: Prescription products with the widest price variances and their manufacturers, 1st quarter, 1989	30
3. U.S. Prescription Drug Products with Highest Rates of Inflation 1985–90	31
4. New Molecular Entities Approved by the Food and Drug Administration, 1985–90	31

SECTION I—PRESCRIPTION DRUG PRICE INFLATION

BACKGROUND

Despite decades of pleas from millions of chronically ill Americans of all ages and their representatives inside and outside of the Congress, the pharmaceutical manufacturing industry has refused to moderate its pricing policies. For over 2½ years, the majority staff of the Senate Special Committee on Aging has been investigating prescription drug prices and methods to contain prescription drug price inflation. This section provides some current data on prescription drug price inflation in the United States.

Finding 1: During the 1980's, at a time when the overall health care inflation rate has more than doubled the general inflation rate, the pharmaceutical inflation rate has exceeded even this seemingly out-of-control health care inflation index (Chart 1). On average, pharmaceutical inflation rose almost *20 percent (18.5 percent)* more each year than medical inflation during this time period.

Finding 2: From 1980–90, while the general inflation was 58 percent, prescription drug price inflation was 152 percent, almost three times the rate of general inflation [1] (Chart 2).

Finding 3: In the face of last year's unprecedented Congressional scrutiny and criticism of drug price inflation, the drug industry not only has maintained but increased the rate of inflation on its products in 1991. During the first 6 months of this year, the overall annualized general inflation rate was 3.3 percent, while the annualized prescription drug inflation was *almost three and a half times* this, a staggering 11.2 percent [2] (Chart 3).

Finding 4: Recent data released by the Bureau of Labor Statistics indicate that prescription drug price inflation is accelerating. In August 1991, while the general inflation rate was 0.2 percent, prescription drug inflation was 1.3 percent, six and one-half times as much. This 1.3 percent increase in prescription drug prices was the largest monthly increase for the last 8 months.

Finding 5: Because of the unprecedented increases in drug product costs, a prescription product that cost the average American $20 in 1980 now costs the average American $53.76. If pharmaceutical manufacturers continue to increase drug prices in the future at the same excessive pace that they have in the past, this $20 pre-

---

[1] Congressional Research Service (CRS) memorandum and personal communications on prescription drug price inflation prepared for the staff of the Senate Special Committee on Aging, July 29, 1991.

[2] Ibid No. 1.

scription drug product will cost $77.06 in 1995 and an unbelievable $120.88 in the year 2000—an increase of over 600 percent (Chart 4).

Alternatively, if drug manufacturers had kept price increases at pace with current general inflation (CPI–U) projections, the same 1980 $20 drug product would only cost $49.72 in 2000, only two and a half times as much. Unfortunately, there are no signs that the drug industry plans to limit its price increases to CPI–U or even the medical care inflation index anytime in the near future.

Finding 6: While prescription drug price increases affect the ability of all Americans to afford medications, the Nation's elderly population continues to be the hardest hit by skyrocketing drug costs. For example, studies have shown that expenditures for prescription drugs represent the highest out-of-pocket medical care cost for three of four elderly Americans. In addition, a recent report by the Congressional Budget Office (CBO) found that 60 percent of Medicare enrollees face potentially catastrophic out-of-pocket expenses, either because they have no supplementary Medicare coverage or because their supplemental coverage does not include prescription drugs. The report suggests that financial risks could be limited for enrollees by including coverage for prescription drugs in the Medicare program.[3]

Finding 7: Since enactment of the Medicaid Prudent Pharmaceutical Purchasing provisions of the Omnibus Budget Reconciliation Act of 1990, there have been reports—most recently confirmed by a September 18, 1991 General Accounting Office report about Department of Veterans Affairs drug prices and by a September 1991 HHS Office of the Inspector General report—that some pharmaceutical ticals with which they have traditionally negotiated reduced prices or discounts. These buyers include hospitals, health maintenance organizations, community health centers, and other Federal purchasers such as the Department of Veterans Affairs and the Department of Defense. It appears that these manufacturers are using the Medicaid rebate law as an excuse to eliminate or sharply reduce the discounts that they have given to other purchasers and to pad their already enormous profit margins.

---

[3] "Restructuring Health Insurance for Medicare Enrollees," Congress of the United States, Congressional Budget Office, August 1991.

SECTION II—PHARMACEUTICAL INDUSTRY'S PROFITABILITY

BACKGROUND

The pharmaceutical industry has distinguished itself as one of the very few recession-proof industries in the United States. Year after year, the pharmaceutical industry has been able to impress Wall Street by posting industry-leading double digit profit margins that dwarf all other industries in the United States. Recent evidence suggests that this trend continues unabated. While Americans have never been critical of an industry making profits, they are growing extremely weary of having the most vulnerable populations of our society underwrite these excessive and unconscionable profits.

Finding 1: While the average Fortune 500 industry in the United States had an average profitability of 4.6 percent in 1990, the average profitability of the top 10 drug companies more than tripled that amount: 15.5 percent [4] (Charts 5 and 6).

Finding 2: In 1990, the pharmaceutical industry led all industries in the United States in the three most commonly used profitability measures [5] (Chart 7).

1. As a *percentage of return on sales,* the pharmaceutical industry's first-rank profitability measure (13.6 percent) is more than three times the average industry's profitability by this measure (4.1 percent).
2. As a *percentage of return on assets,* the pharmaceutical industry's first-rank profitability measure (13.1 percent) is three times the average industry's profitability by this measure (4.8 percent).
3. As a *percentage of return on stockholder's equity,* the pharmaceutical industry's first-rank profitability measure (26.4 percent) is more than twice the average industry's profitability by this measure (13 percent).

Finding 3: A drug industry analyst recently predicted that the pharmaceutical industry's profits will climb at a staggering rate of 18 percent each year over the next few years as a result of the upcoming introduction of some extremely high-priced new drug products to the market. As a result, he forecasts that the average pharmaceutical manufacturer's revenue will increase 15 percent this year and 14 percent next year.[6]

---

[4] The 1991 Business Week 1000.
[5] Ibid No. 4.
[6] Fortune Magazine, July 15, 1991.

SECTION III—PHARMACEUTICAL INDUSTRY'S MARKETING EXCESSES

BACKGROUND

Excessive sales, marketing and advertising expenditures by pharmaceutical manufacturers substantially contribute to high drug prices in the United States. A reduction in these expenditures would significantly reduce the cost of pharmaceutical products for all Americans.

Because the drug industry has become very proficient in developing an excessive number of "me-too" drug products—that is, drug products that offer little or no therapeutic advance over those that are already on the market—manufacturers invest substantial financial resources on marketing to convince health professionals that their new drugs really do make a significant contribution to the drug therapy arsenal. Recent data clearly indicate that drug manufacturers continue to inflate drug prices higher and higher to pay for their lavish and expensive marketing and advertising campaigns.

Finding 1: In 1991, according to the pharmaceutical industry's own data, drug manufacturers will spend $1 billion more on marketing and advertising than it will on research and development. In 1991, total research and development expenditures will be $9 billion and total sales and marketing expenditures will be $10 billion [7] (Chart 8).

Finding 2: In 1991, as a percent of an average manufacturer's sales, advertising and marketing expenditures will constitute, on average, more than research and development expenditures. Advertising and marketing expenditures for the average company will be 25 percent of sales while research and development expenditures will be 22.5 percent of sales (Chart 8).

Finding 3: For the average pharmaceutical company, expenditures on sales and marketing will increase faster as a percent of sales than expenditures on research and development. Sales and marketing expenditures are expected to increase 15 percent, while research and development expenditures are expected to increase 13.6 percent (Chart 9).

Finding 4: As shocking as these drug industry compiled facts are, the ongoing Aging Committee investigation has found that many of the dollars that drug manufacturers claim are spent on research of new pharmaceutical products are actually spent on marketing research. This research is unrelated to the purpose for the research

[7] Forbes Magazine, April 15, 1991.

credit; that is, encouraging the development and discovery of new drugs. These so-called "research" activities help the companies collect the data they need to design their lavish marketing and promotional campaigns. Such marketing research expenditures are lumped into claimed research and development expenditures, and manufacturers are then able to write them off at a significant cost to the American taxpayer.

- Some drug manufacturers disguise postmarketing studies as research studies, and use these studies to promote unapproved uses of their drugs to physicians. Because manufacturers may not directly advertise unapproved uses of their products to physicians, they use this route to promote these unapproved uses to prescribers.

Finding 5: Not only does the drug industry waste a significant amount of dollars on marketing and advertising, hearings held before the Senate Labor and Human Resources Committee in December 1990 highlighted abusive marketing and promotional practices in which some drug manufacturers engage to promote their products. The Committee's Chairman concluded: "Pharmaceutical companies are spending larger sums on questionable tactics that subvert basic standards of medical standards, tempting doctors with lavish vacations, gifts, and cash payments." [8]

Examples:

- Drug manufacturers sponsoring all-expense paid "educational symposia" for physicians and their spouses to plush resort locations.
- Manufacturers giving physicians the chance to win expensive tickets to prestigious entertainment or sporting events.
- Drug manufacturers offering physicians cash payments for prescribing a certain amount of a particular manufacturer's drug over a period of time. The payments are often disguised as remuneration for the physician's participation in a "clinical trial" for the drug.

Finding 6: One pharmaceutical company executive estimated that his company spends at least $100 per physician per product on promoting their drugs. According to a 1989 *New York Times* article, pharmaceutical manufacturers spend approximately $5,000 per physician on marketing and advertising.[9]

Finding 7: Recently, as reported in the September 7, 1991, *Washington Post,* the Food and Drug Administration found evidence that one major pharmaceutical manufacturer is spending substantial sums of money on promoting the company's drugs that have yet to be approved by the agency. Doctors were offered free dinners and $100 gift certificates for medical books in return for attending a meeting and discussion session about these unlicensed products. In addition to this being an example of how some drug manufactur-

---

[8] Senate Labor and Human Resources Committee hearing on Advertising, Marketing, and Promotional Practices of the Pharmaceutical Industry, December 11, 1990.
[9] New York Times Magazine "Pitching Doctors", November 5, 1989.

ers engage in questionable and even potentially illegal marketing activities (Federal law prohibits drug companies from promoting drugs that have not yet been approved by the FDA), it is yet another example of the amount of money that drug manufacturers waste on marketing and promoting their products.[10]

[10] Washington Post, "FDA Will Probe Smith Kline on Pitch for Unlicensed Drugs," September 7, 1991.

SECTION IV—UNITED STATES DRUG PRICES VERSUS OTHER INDUSTRIALIZED NATIONS

PART 1: SPECIFIC COMPARISONS OF DRUG PRICES BETWEEN THE UNITED STATES, CANADA, AND EUROPE

BACKGROUND

A 1989 report of the majority staff of the Special Committee on Aging reported that Americans pay over 50 percent more than Europeans for the same prescription drug products. Recent data indicate that there continue to be wide discrepancies between prices paid by Americans for drugs and prices paid by Europeans and Canadians for the same prescription drugs. This section examines some of the differences in drug prices between the United States and other industrialized nations, and examines the wide price differences on specific drugs between Canada and the United States.

Finding 1: Although analysis on this subject differs, there is no question that Americans continue to pay extraordinarily higher prices on almost all brand name prescription drugs than do citizens of other industrialized nations.

- Another analysis of prescription drug prices in seven European countries, published in 1990 by the *Farmindustria*, the Italian Pharmaceutical Manufacturers Association, shows that Americans pay over three times more than the average European pays for prescription drugs [11] (Chart 10).
- According to the Office of the Inspector General's March 1991 study comparing Canadian and European drug prices with U.S. drug prices, the average American citizen pays 62 percent more for prescription drugs than the average Canadian citizen and 54 percent more than the average European citizen. [12]

Finding 2: If State Medicaid agencies had access to prices that the pharmaceutical industry makes widely available in Canada (and other countries), State Medicaid agencies and American taxpayers would annually pay an estimated $474 million less for brand name drugs used in the Medicaid programs. Of this amount, $261 million would be Federal savings and $213 million would be State savings.[13]

Finding 3: If all U.S. citizens had access to the prices that American drug manufacturers make available to other Western, industri-

---

[11] Indicatori Farmaceutici, June 1990. Annual report produced by the Italian Pharmaceutical Manufacturers Association.

[12] Department of Health and Human Services. Office of the Inspector General. "Strategies to Reduce Medicaid Drug Expenditures." March 27, 1991.

[13] Ibid No. 12.

46-236 O - 91 - 2

alized nations, billions of precious health dollars could be saved by acutely and chronically ill Americans of all ages, health care institutions, such as hospitals and HMOs, health care insurance plans, and taxpayers.

Finding 4: Not only do Americans pay substantially higher prices for drugs than Canadians and Europeans, the most significant drug price inflation increases in the United States occur on the same products for which Americans already pay substantially more than Canadians.

Examples: (See tables 1 and 2).

- While the average American had to already pay 277 percent more than the average Canadian for Flint's *Synthroid* in 1989, the company also forced the average American to swallow a 22.2 percent price increase for the product between 1989 and 1990.
- Wyeth-Ayerst not only charged Americans 233 percent more than Canadians for *Premarin* in 1989, but between 1989 and 1990, the company raised the price 19.7 percent.
- Parke-Davis charged the average American 322 percent more than the average Canadian for *Dilantin* in 1989, and has also raised the price 19 percent between 1989–90.
- Wyeth-Ayerst charged the average American 682 percent more than the average Canadian for *Ativan* in 1989, and has increased the price of the product almost 80 percent between 1985 and 1990.

PART 2: CANADA—A CASE EXAMPLE OF HOW A DRUG PRICE REVIEW BOARD CONTAINS DRUG COSTS

Background

Price negotiations between the drug manufacturers and the health care systems of the various Canadian provincial governments help to produce lower costs for some pharmaceuticals in Canada. However, these negotiations are not the primary reason for lower drug costs in Canada. The creation of a Canadian Patented Medicine Prices Review (CPMPR) Board in 1987 has made the most significant contribution to restraining prescription drug price inflation in that nation. It is important to note that a national health care system is not a prerequisite for the establishment of this Board because the Board not only helps to contain costs for government purchasers, but for private payors as well.

Finding 1: While drug product inflation has been running at three times the rate of general inflation (CPI–U) in the United States over the last 10 years, Canadian prescription drug price inflation (CPI–RX) has been much more moderate, and has even decreased over the last 4 years [14] (Chart 11).

---

[14] Third Annual Report of the Canadian Patented Medicine Prices Review Board, December 31, 1990.

Finding 2: From January 1983 until December 1987, before the CPMPR Board was created, the pharmaceutical component of the Canadian Industrial Products Price Index (IPPI) increased by an annual average rate of 7.1 percent, while the Canadian CPI-U increased at an annual average rate of 4.3 percent. (The IPPI index measures the prices of both patented and off-patented drugs.) After establishment of the Board, from December 1987 until August 1990, the pharmaceutical component of the Canadian IPPI increased much less than the January 1983–December 1987 period (5.5 percent per year), in spite of the fact that the Canadian CPI-U increased to 4.7 percent during that same time period.[15]

Finding 3: The CPMPR Board ties prescription drug price increases to increases in the Canadian consumer price index. If the Board finds little justification for the price increase or the excessive launch price of a new drug product, it can remove or shorten the period of market exclusivity of the drug being sold at an excessive price.[16] The Board works in the following manner:

1. The CPMPR Board is not a drug price control body; it is a drug price review body. The pharmaceutical industry in Canada is free to charge whatever price it wishes for its products. However, that price is subject to review by the board to determine whether it is "excessive."

2. In determining whether a price on a drug is excessive, the CPMPR Board considers the following factors:

- the 5-year pricing history of the drug;
- the prices of other drugs in the same therapeutic class;
- the prices of the drug and others in the same therapeutic class in other developed, industrialized countries; and
- the Canadian CPI-U.

3. The CPMPR Board has adopted a "voluntary" enforcement mechanism. It is designed to encourage drug manufacturers to price their products at levels which are not excessive, using the guidelines above. When potentially excessive prices are identified, drug manufacturers are given the opportunity to bring prices in line with the Board's guidelines. To date, this voluntary enforcement approach has helped to restrain both drug price inflation on existing products and the launch prices on new drug products. However, the CPMPR Board's ultimate remedy is to remove the period of market exclusivity for a drug being sold at an excessive price.

Finding 4: While drug manufacturers have been increasing prices in the United States at three times the CPI-U over the last 10 years, in Canada, pharmaceutical manufacturers have indicated

---

[15] Ibid No. 14.

[16] "Price Review in Canada: The Role of the Patented Medicine Prices Review Board." An address given by Wayne Critchley, Executive Director, Patented Medicine Prices Review Board, Toronto, Ontario, Canada, November 8, 1990.

that they are prepared to restrict price increases in that country to changes in the CPI-U.[17]

Finding 5: Even with the moderating of drug price inflation in Canada, the pharmaceutical industry has made a commitment to increase its research and development spending in Canada by 10 percent by 1996, indicating that drug companies can still invest in meaningful research and development without charging excessive prices for prescription drugs.[18]

[17] Ibid No. 16.
[18] Ibid No. 16.

SECTION V—DRUG INDUSTRY'S BILLION DOLLAR NON-RESEARCH ORIENTED TAX BREAK

BACKGROUND

It is fairly well known that the pharmaceutical industry receives hundreds of millions of dollars in tax credits and subsidies for researching and developing new pharmaceutical products. Few Americans are aware, however, of the fact that the pharmaceutical industry is, by far, the leading benefactor of a generous, non-research and development oriented tax windfall credit called the Possessions Tax Credit (as provided in Internal Revenue Code Section 936). The Section 936 Tax Credit provides an income tax exemption for business income earned in Puerto Rico and other U.S. territorial possessions.

The stated purpose of the credit is to "assist the U.S. possessions in obtaining employment-producing investments by U.S. corporations," and hence stimulate economic development and jobs.[19] Although the stated purpose of Section 936 is meritorious, its terms provide no direct incentives to generate jobs. Instead, the credit rewards the generation of income in the territorial possessions. Particularly at a time when prescription drug price increases are tripling the general inflation rate, the non-research based tax subsidization of extraordinarily profitable drug companies which are extremely capital intensive rather than labor intensive seems highly questionable.

Finding 1: Nineteen pharmaceutical firms accounted for almost half of all the Section 936 Tax Credits claimed by all U.S. manufacturing companies between 1983–87.

- During that time, these credits have resulted in tax savings of over $5 billion to the drug industry, or 45 percent of all the Section 936 Tax Credits claimed by all U.S. industries. The credit was worth at least $1.4 billion to the drug industry in 1987. The Congressional Research Service estimates that the credit was worth $2 billion to the drug industry in 1990.

Finding 2: The Section 936 Tax Credit contributes to the drug industry's already overflowing coffers and substantially reduces the pharmaceutical industry's tax payments to the Federal Treasury.

- According to a recent Congressional Research Service report, drug companies pay taxes at a level that is lower than the average for U.S. firms. The study said that the 1987 effective tax rate for pharmaceutical firms was 22.14 percent, com-

[19] CRS Memorandum on Possessions Tax Credit prepared for the staff of the Senate Special Committee on Aging, May 20, 1991.

pared to 24.72 percent for all firms. The same study indicated that the Section 936 Tax Credit had a dramatic effect on reducing the taxes paid to the Federal Government by the drug manufacturing industry. The credit reduced the effective tax rate of drug firms by an average of almost 9 percentage points.[20]

Finding 3: The Section 936 Tax Credit is an inefficient and very costly method of promoting jobs in the pharmaceutical industry in Puerto Rico.

- Recent data indicate that, on average, the pharmaceutical industry receives a Section 936 tax benefit worth $57,761 per employee that they hire in Puerto Rico. The average salary of a pharmaceutical industry employee in Puerto Rico is only $21,180, meaning that the average pharmaceutical company receives a tax credit that is 264 percent more than the average salary that they pay [21] (Chart 12).
- Other industries manufacturing in Puerto Rico receive much more reasonable Section 936 tax credits as compared to the pharmaceutical industry. For example, the next highest 936 tax benefit received by an industry manufacturing in Puerto Rico is the $20,611 per employee received by the machinery industry, which is $37,150 less than the average 936 tax benefit of the pharmaceutical industry. The textile industry and the apparel industry both receive a benefit worth $3,295 per employee, while the leather products industry receives a benefit of $3,567 per employee [22] (Chart 13).

Finding 4: There is no evidence to suggest that the multi-billion dollar taxpayer funded Section 936 Tax Credit that Americans bestow on the pharmaceutical industry each year results in lower drug prices to the American consumer.

Finding 5: Most of the companies who have manufacturing operations in Puerto Rico have added little to the therapeutic arsenal over the past 5 years, while reaping significant tax breaks from the Section 936 Tax Credit (see Table 2).

- Only four New Molecular Entities (NMEs) of significant therapeutic gain have been developed since 1985 by the 19 pharmaceutical companies that have manufacturing operations in Puerto Rico.
- Five of the 19 companies with manufacturing operations in Puerto Rico have not brought a single new pharmaceutical product to market since 1985.
- Of 47 new products brought to market by pharmaceutical companies with manufacturing operations in Puerto Rico, almost 60 percent have been rated as having little or no therapeutic gain.

---

[20] Ibid No. 19.
[21] Department of the Treasury. Operation and Effect of the Possessions Corporation System of Taxation—6th Report, March 1989.
[22] Ibid No. 21.

Finding 6: The pharmaceutical industry uses the Section 936 Tax Credit more intensely than any other industry in the United States.

- One measure of the value of this credit to an industry is to compare the value of the credit as a percent of the assets of an industry. Data for the period 1983–87 show that the tax credit contributed 1.654 percent to the pharmaceutical industry's assets, which was 20 times that of other manufacturing industries that claimed the credit, and 92 times that of all corporations that claimed the credit. A recent Congressional Research Service report concluded that, "compared to other industries, the pharmaceutical industry's use of the possessions tax credit is particularly heavy." [23]

Finding 7: The attractiveness of the Section 936 Tax Credit has lured U.S. mainland jobs to Puerto Rico.

- A tax incentive as generous as the Section 936 Tax Credit is an attractive incentive for U.S. companies to transfer jobs to Puerto Rico. A study entitled "The Impact of Section 936 on Manufacturing Jobs in the Mainland United States: Case Studies", prepared by the Midwest Center of Labor Research, documents thousands of mainland jobs which have been transferred to Puerto Rico. Twenty-five cases of plant closings and major layoffs were reviewed involving 21 different companies. Thirteen cases involved a direct and complete transfer of jobs from the mainland to Puerto Rico. The remainder of the cases in the study shows a transfer of jobs to multiple locations, including Puerto Rico. It is important to note that representatives of beneficiaries of the Section 936 Tax Credit strongly dispute this study. They claim that the mainland plant closings were business decisions made exclusive of the attractiveness of the Section 936 Tax Credit, and further, that the Section 936 Tax Credit actually creates jobs on the mainland. Regardless, it is clear that this issue certainly merits further study.

[23] Ibid No. 19.

SECTION VI—HIGH DRUG PRICES PRODUCE FEW BREAKTHROUGH DRUGS

Background

America's drug manufacturers argue that high drug prices are needed in this country to fund the research and development of new pharmaceutical products which, they contend, is a very expensive, risky, and uncertain business. However, as previous sections illustrate, high prices, profits, and tax subsidies are producing many more slick and expensive marketing campaigns than they are truly significant breakthrough drug products.

Finding 1: As illustrated in Tables 3 and 4, drug manufacturers that have either brought few if any new drug products to the market over the last 5 years *OR* that have few if any new drug products in the research pipeline, resort to frequent and excessive price increases as a mechanism to maintain their high profitability.

Finding 2: The highest prescription drug price inflation occurs on drugs that have been on the market for many years, for which research and development costs have long-since been recovered.

Examples: (See Tables 3 and 4).

- Tylenol with Codeine (a widely used moderate pain killer), manufactured by McNeil Pharmaceuticals, has been on the market since 1977, but has had cumulative price inflation of 128.5 percent since 1985, an average of 16 percent each year. NcNeil has not brought a new molecular entity to market in the last 5 years.
- Synthroid (a thyroid replacement therapy), manufactured by Flint, has been on the market since 1938. The product had a cumulative price increase of 104 percent since 1985, an average of 15.5 percent each year. Flint has not brought one new molecular entity to market in the last 5 years.
- Premarin (an estrogen replacement therapy) and Inderal (a heart medication), both manufactured by Wyeth-Ayerst, have been on the market since 1956 and 1967, respectively. Since 1985, Premarin went up in price 131 percent, an average of 21.5 percent each year, and Inderal went up in price 112.4 percent, an average of 17.1 percent each year. Before the companies merged, Wyeth brought one new molecular entity to market. However, Ayerst has not brought a new molecular entity to market in the past 5 years.
- Dilantin (an antiepileptic drug), manufactured by Parke-Davis, has been on the market since 1953. Since 1985 it has gone up in price 69 percent, an annual average increase of

over 11 percent. The company has not brought a new molecular entity to market in the last 5 years.

Finding 3: It is possible for a pharmaceutical manufacturer to maintain profitability, bring new drugs to the market, and refrain from charging excessive inflation. For example, Merck Sharp and Dohme, the world's largest and most research-intensive pharmaceutical manufacturer, brought 8 new molecular entities to market between 1985 and 1990 (see Table 2), voluntarily limits its annual price increases to changes in the CPI–U, and was still able to maintain significant profitability (see Chart 6).

CONCLUSION: POLICY OPTIONS

BACKGROUND

For years, Congress has raised concerns about skyrocketing prescription drug price inflation. It was not until last year, however, that Congress passed legislation that took a substantive step toward addressing the problem. As a result, the $5 billion Federal-State Medicaid program, serving our Nation's poor and disabled, will no longer be forced to pay the highest prices in the market for prescription drugs.

During the debate surrounding the Medicaid drug rebate law, drug manufacturers frequently stated that the 1980's represented an anomaly. They said that drug price inflation that doubled and tripled the general inflation rate would not continue, and gave many in Congress the impression that they had received the message that drug cost increases of the past would no longer be tolerated. Sadly, however, if current trends continue, and as this report illustrates, it appears that the 1990's not only will be a price inflation encore, but may well surpass the unacceptable performance of the 1980's.

Attempting to shame the drug manufacturing industry into being responsive to the needs of the American public is obviously not working. Reasonable but concrete proposals, therefore, must be advanced that more effectively and fairly deal with the drug pricing problem. The following recommendations are offered in that spirit.

RELATING TO PHARMACEUTICAL ACCESS AND COST CONTAINMENT MECHANISMS IN THE UNITED STATES

Recommendation 1: Because drug manufacturers are able to reap substantial tax breaks from the use of the Section 936 Tax Credit (Possessions Tax Credit), with little if any benefit to the American public, the Congress should enact legislation that would reduce the Section 936 Tax Credits of a drug manufacturer that inflates its U.S. drug prices higher than a certain percentage of the Consumer Price Index (CPI-U). Taxpayer-underwritten financial rewards—such as tax subsidies—should be linked to acceptable and achievable performance standards.

Recommendation 2: Any revenue achieved through the Section 936 Tax Credit reform as outlined in Recommendation 1 (and directly attributable to excessive and inflationary pricing practices of drug manufacturers) should be directed to a new Federal Prescription Drug Trust Fund. This new Trust Fund would be used to establish a Medicare Outpatient Prescription Drug Demonstration Project. Revenue from the Trust Fund could also be used to target

special populations of Medicare beneficiaries, such as those served by community health care centers.

Recommendation 3: The Secretary of the Treasury, acting in consultation with the Secretary of the Department of Health and Human Services, should be required to submit an annual report to Congress on all the Federal subsidies, grants, and tax incentives given to the pharmaceutical industry, and make an assessment of whether these Federal subsidies are being used in the most efficient manner by the pharmaceutical industry.

Recommendation 4: The Secretary of the Treasury, acting in consultation with the Secretary of the Department of Health and Human Services, should assess the advisability of developing a program that would restructure pharmaceutical product research and development tax credits so that they are based on the therapeutic innovativeness of the products that are brought to market. Drug companies that consistently bring few or no breakthrough drugs to the market and produce medications that largely duplicate what is already available should not be rewarded to the same degree as those manufacturers that do.

Recommendation 5: The Secretary of the Department of Health and Human Services, acting in consultation with the Commissioner of the Food and Drug Administration, should develop a program that identifies and makes public the role of the Federal Government in bringing each new drug and biological to the market. In instances in which there is a significant Federal role in bringing a new product to the market, the Secretary (or another Federal agency) should seek to be a co-licensee of the product with the pharmaceutical manufacturer.

Recommendation 6: The Secretary of Health and Human Services should conduct a study to determine the feasibility and advisability of establishing in the United States a Pharmaceutical Products Price Review Board, similar to the one that has been established in Canada. The Board would provide a mechanism to insure that the American public is paying a fair, reasonable price for its pharmaceutical products. In so doing, the Secretary should determine how best to have manufacturers justify domestic pricing practices on existing and new drug products, especially where there are wide discrepancies between international and domestic drug prices. To encourage voluntary compliance, the Secretary should determine the feasibility of giving the board the authority to limit market exclusivity on certain drugs whose manufacturers refuse to price their products responsibly.

Recommendation 7: Broader-based, Congressionally mandated studies are underway to determine if the pharmaceutical manufacturers are responding to the Medicaid rebate law's "best price" provision by excessively raising prices to pharmaceutical purchasers such as hospitals and HMOs. If this is the case, Congress should amend the Medicaid rebate law so that the rebate is based on a "best price" anchored to a certain date in time, increased each year by changes in inflation. This approach was advocated in the Medicaid Anti-Discriminatory Drug Price and Patient Benefit Res-

toration Act of 1990, since it would maximize Medicaid savings on prescription drugs and would make it extremely difficult for drug manufacturers to use the Medicaid law as the cover for increasing prices to other drug purchasers.

Recommendation 8: To protect smaller, non-Medicaid Federal purchasers, such as the Department of Veterans Affairs, the Department of Defense, and community health centers from excessive prescription drug price inflation, Congress should enact legislation that meets or exceeds the inflation protection now being given to Medicaid, the largest Federal purchaser.

RELATING TO INTERNATIONAL PHARMACEUTICAL PRICES

Recommendation 1: As a condition of selling pharmaceuticals to Federal Government agencies and health care programs, each pharmaceutical manufacturer should be required to report annually to the Federal Government on the prices that it charges for its pharmaceuticals in other industrialized nations.

Recommendation 2: As an alternative to anchoring the Medicaid rebate price to a certain date and indexing it to inflation, Congress should consider enacting legislation that would base the Medicaid Prudent Pharmaceutical Purchasing program's rebate level on the "best price" that a manufacturer sells its drugs to other Western industrialized nations, such as Canada or European countries. Such a provision would substantially increase State and Federal Medicaid drug program savings, and would negate any rationale for manufacturers to blame the Medicaid law as the reason for increasing prices to other domestic pharmaceutical purchasers, since Medicaid's "best price" would not be based on a domestically determined price.

Recommendation 3: The Secretary of the Department of Health and Human Services should report to Congress on why prescription drug prices and prescription drug inflation are so much lower in other industrialized nations. In so doing, the Secretary should examine how other industrialized nations, such as Germany, are addressing the problem of prescription drug price inflation to determine what applicability, if any, their approaches could have in the U.S. health care system.

Chart 2

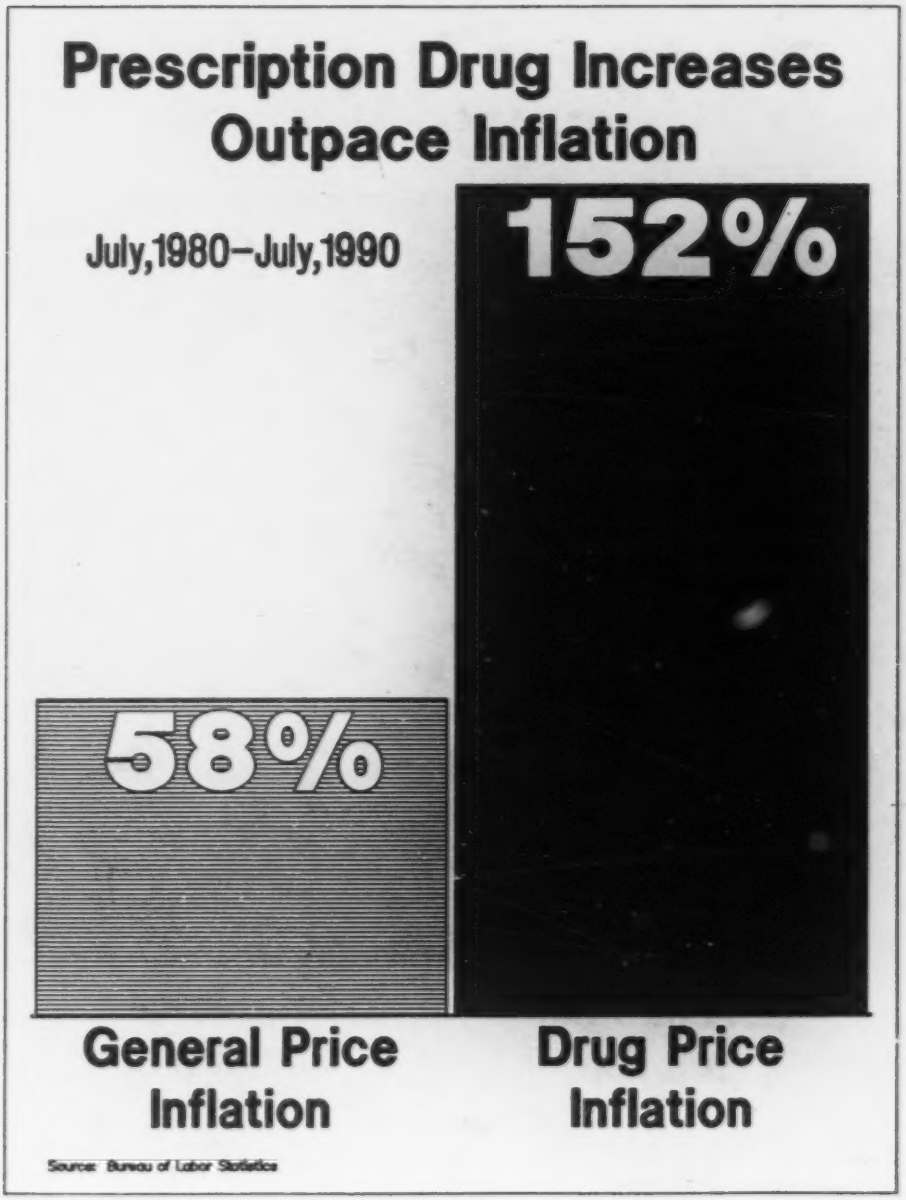

Prescription Drug Increases Outpace Inflation
July,1980–July,1990
152%
58%
General Price Inflation
Drug Price Inflation
Source: Bureau of Labor Statistics

Chart 3

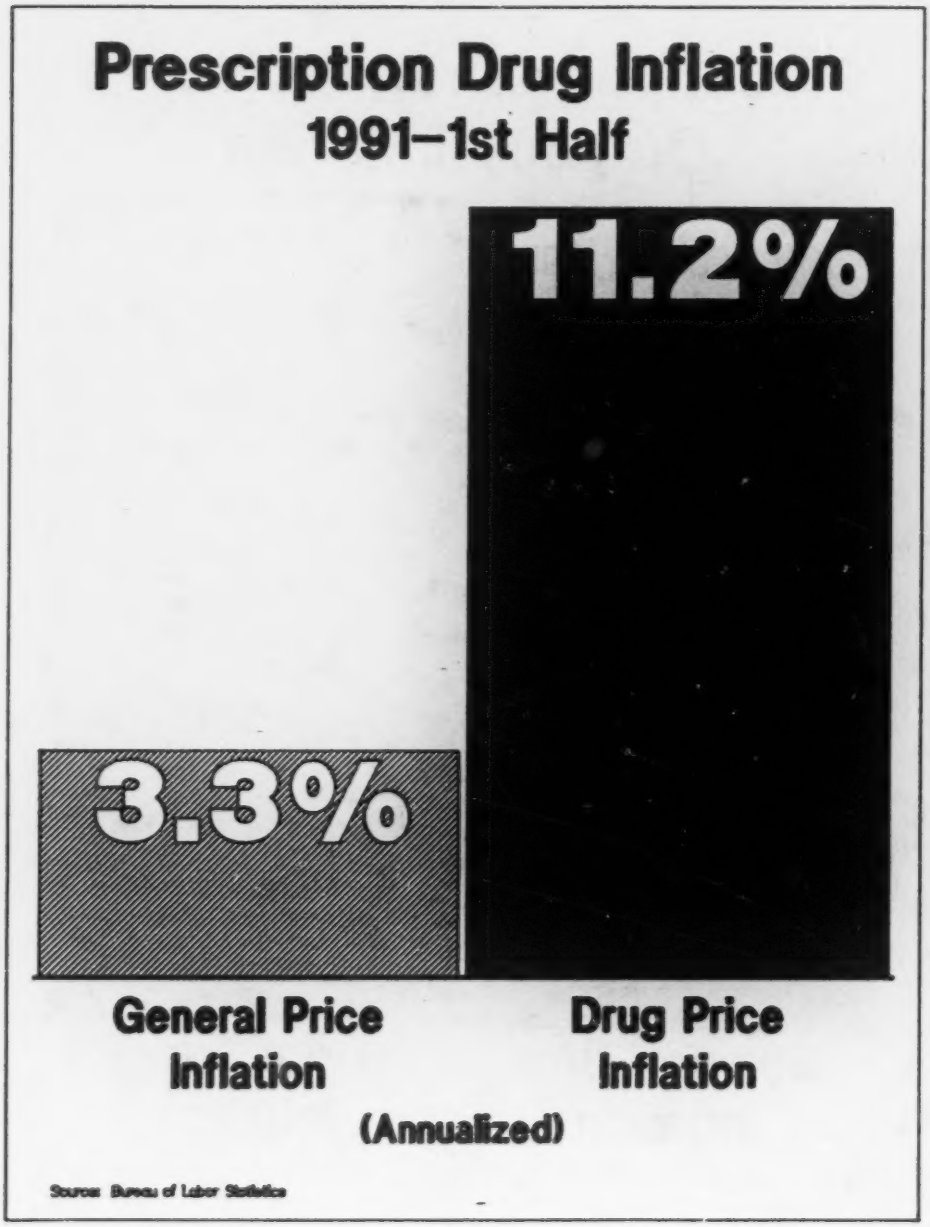

Prescription Drug Inflation
1991–1st Half
11.2%
3.3%
General Price Inflation
Drug Price Inflation
(Annualized)
Source: Bureau of Labor Statistics

Chart 5

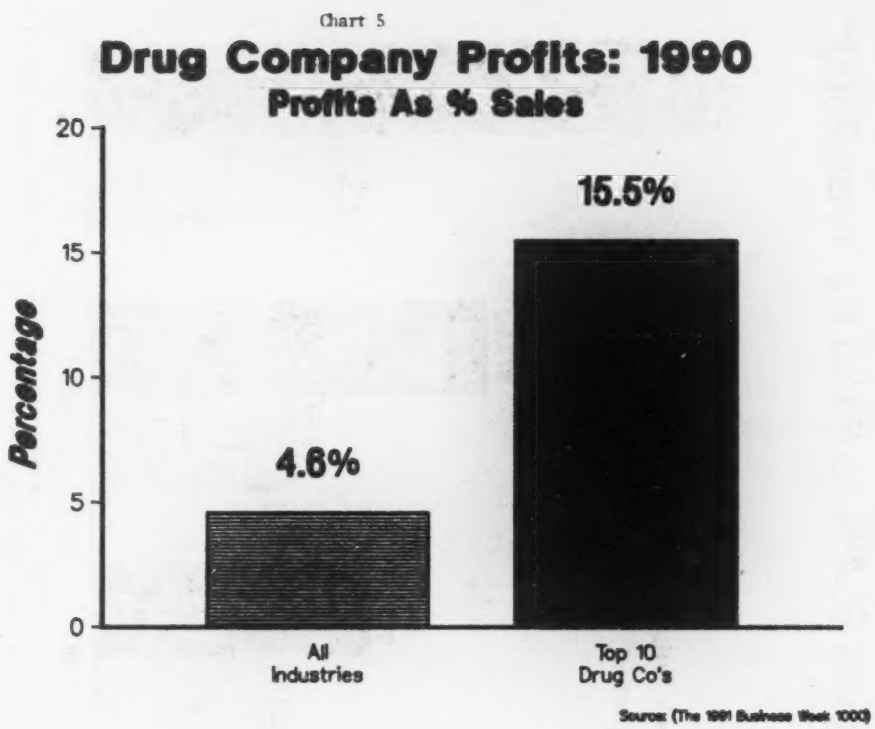


Chart 6

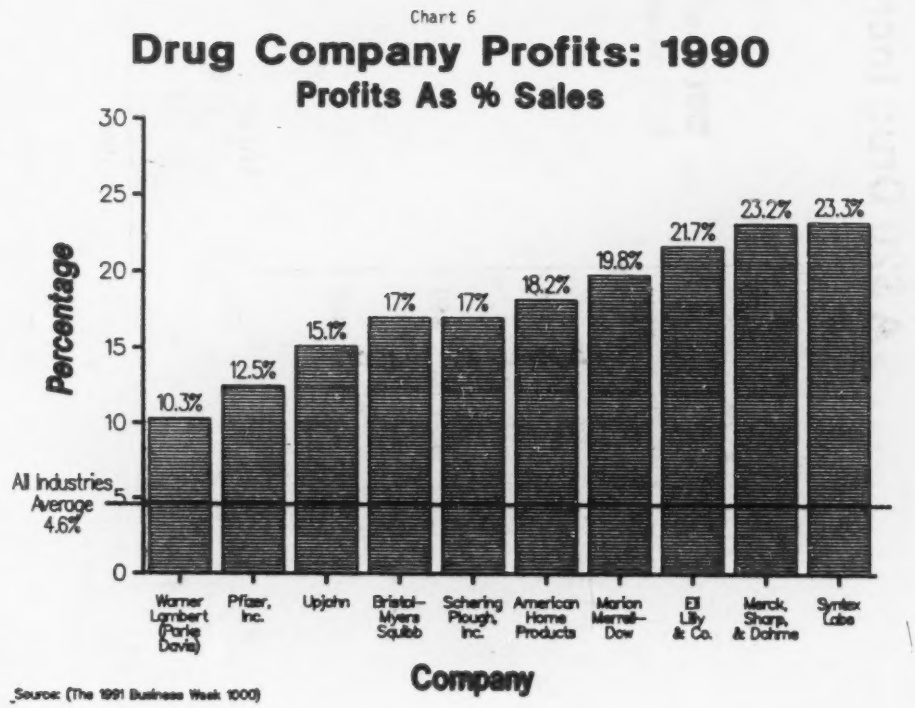


Chart 1

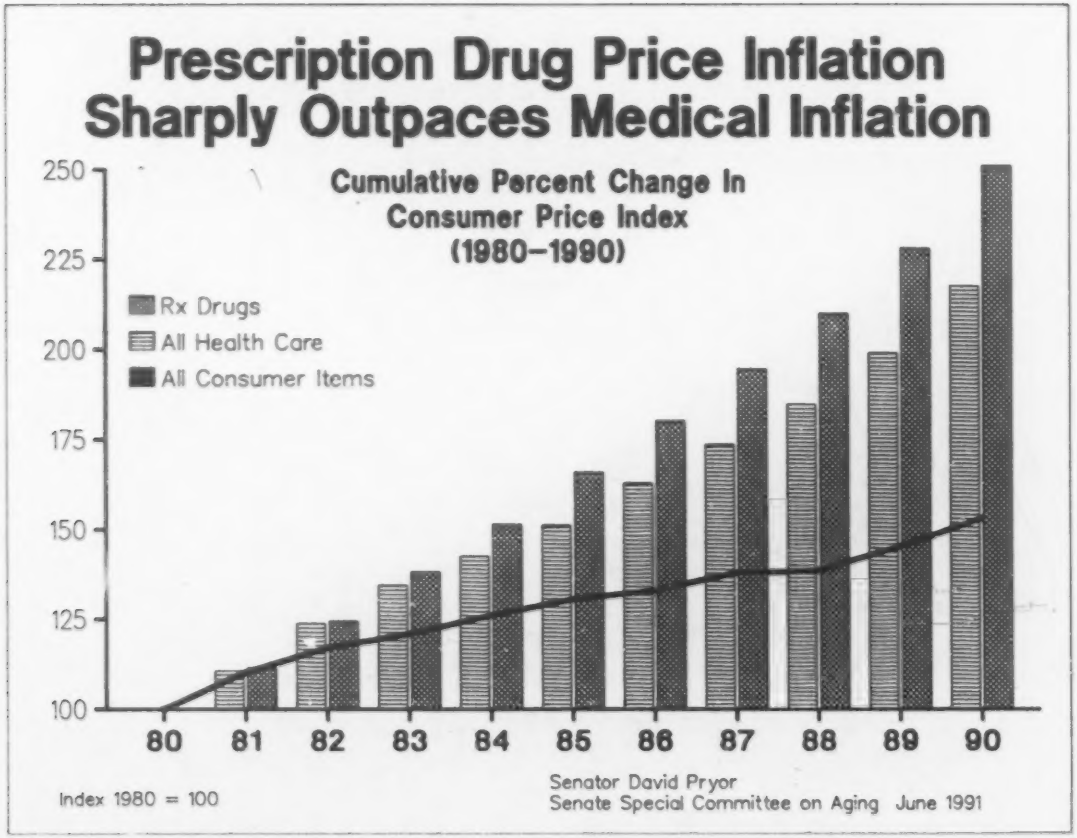
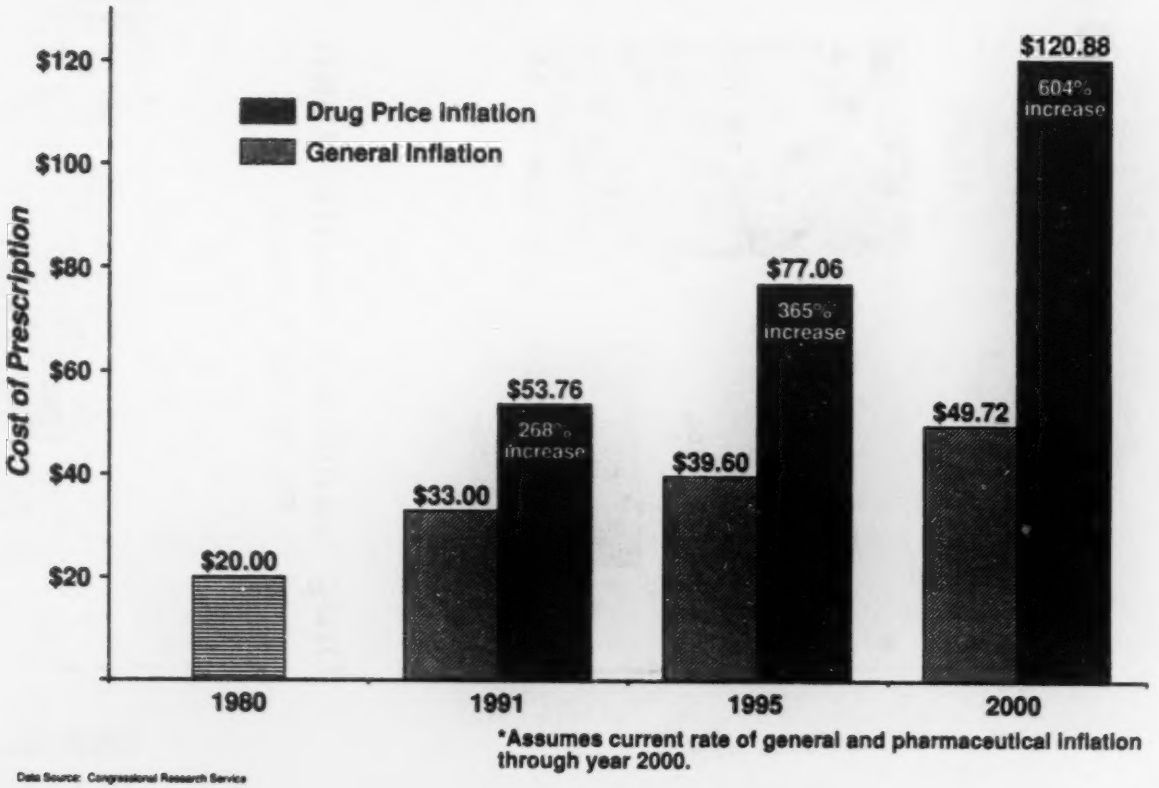

Prescription Drug Price Inflation
Sharply Outpaces Medical Inflation
Cumulative Percent Change In
Consumer Price Index
(1980–1990)
Rx Drugs
All Health Care
All Consumer Items
250
225
200
175
150
125
100
80
81
82
83
84
85
86
87
88
89
90
Index 1980 = 100
Senator David Pryor
Senate Special Committee on Aging June 1991

Chart 4

A $20 Drug Increases 604% to $120 by Year 2000*

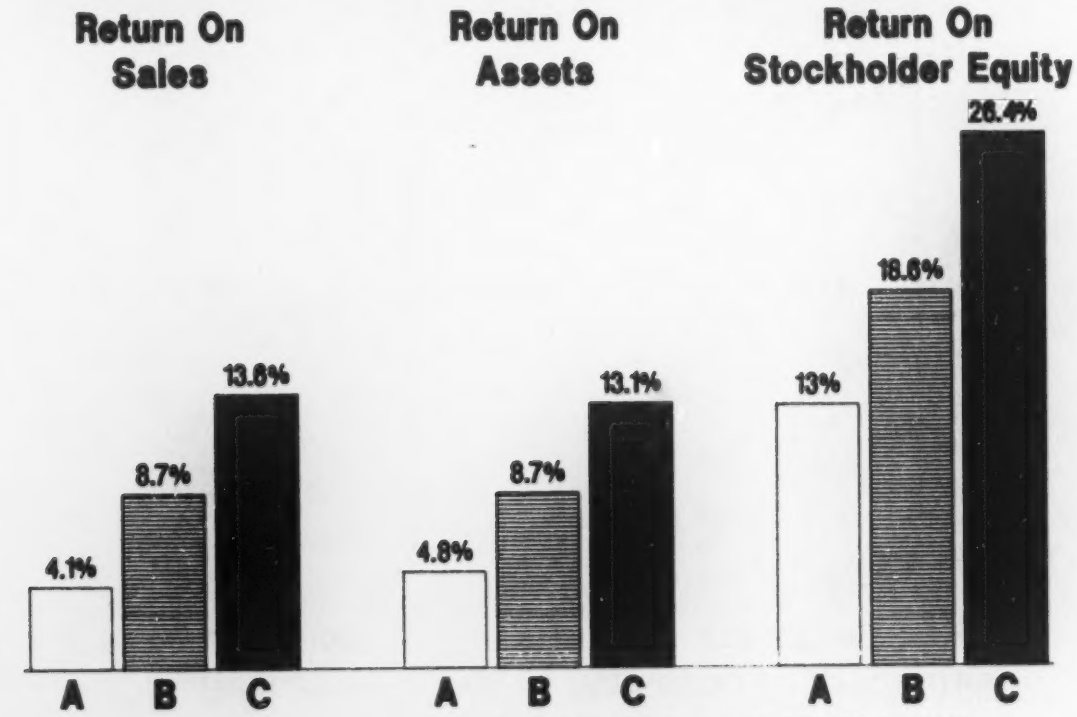


*Assumes current rate of general and pharmaceutical inflation through year 2000.

Data Source: Congressional Research Service

Chart 7

Profitability Of The Pharmaceutical Industry 1990

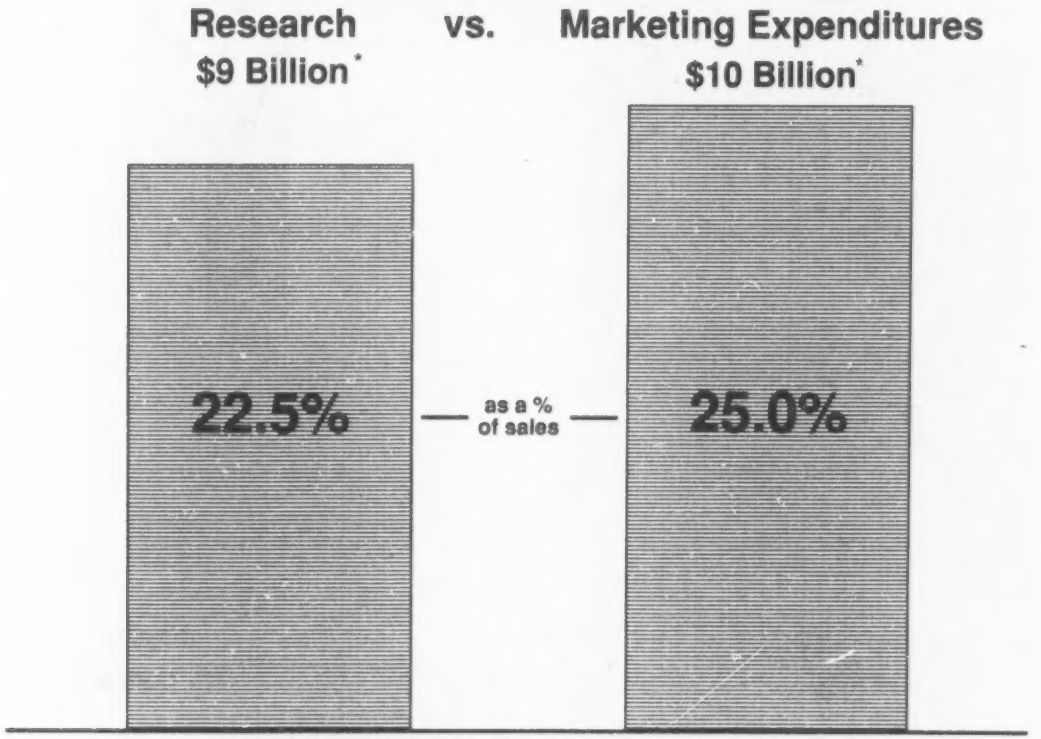


A– Fortune 500 Company's AVERAGE Profitability
B– Second Most Profitable Industry
C– Pharmaceutical Industry (N.B. ranked #1 in each category)

Source: Fortune Magazine, April 1991

Chart 8

Drug Manufacturers – 1991



Represents percent of total sales expected to be spent on R&D and sales and marketing in 1991.

Source: Forbes Magazine, April 15, 1991, based on information provided by the Pharmaceutical Manufacturers Association

* Projected for 1991

TABLE 1.—UNITED STATES VERSUS CANADIAN PRESCRIPTION DRUG PRICES, 1ST QUARTER, 1989 PRESCRIPTION PRODUCTS WITH THE WIDEST PRICE VARIANCES AND THEIR MANUFACTURERS

Drug, quantity, manufacturer, and generic name	U.S. price (1989) [1]	Canadian price (1989) [2]	In percent		
			U.S. versus Canada percent difference (1989)	U.S. price inflation (1985–89) [3]	U.S. price inflation (1989–90) [3]
Ativan 1 mg, 100 tablets (Wyeth-Ayerst) [lorazepam]	$48.96	$7.18	682	66.7	8.0
Keflex 500 mg, 30 capsules (Eli Lilly) [cephalexin]	55.26	16.59	333	51.4	8.0
Valium 10 mg, 60 tablets (Roche Labs) [diazepam]	24.84	8.35	297	80.7	9.5
Halcion 0.25 mg, 100 tablets (Upjohn Co.) [triazolam]	42.66	14.61	291	60.7	18.9
Restoril 15 mg, 100 capsules (Sandoz, Inc.) [flurazepam]	37.50	13.21	283	76.7	10.3
Synthroid 0.025 mg, 100 tablets (Flint) [levothyroxine]	10.31	3.72	277	59.8	22.2
Diabeta 5 mg, 30 tablets (Hoechst) [glyburide]	10.00	4.11	243	33.3	7.5
Ventolin 4 mg, 100 tablets (Schering-Plough) [albuterol]	34.93	15.56	224	60.2	9.0

[1] Based on March 1989 U.S. price data, First Data Bank: Drug Information Data.
[2] Canadian prices are reported in U.S. dollars, based on March, 1989 conversion rate. Canadian prices are the average of prices from the January 1989 versions of two provincial drug lists: Quebec's List of Medications and Ontario's Drug Benefit Formulary.
[3] U.S. price inflation based on price changes from December 12, 1985, to December 31, 1990, using prices from Medispan's Master Drug Data Base.

TABLE 2.—UNITED STATES VERSUS CANADIAN PRESCRIPTION DRUG PRICES, 1ST QUARTER, 1989 PRESCRIPTION PRODUCTS COMMONLY USED IN THE UNITED STATES AND THEIR MANUFACTURERS

Drug, quantity, manufacturer, and generic name	U.S. price, (1989) [1]	Canadian price (1989) [2]	In percent		
			United States versus Canada percent difference (1989)	U.S. price inflation (1985–89) [3]	U.S. price inflation (1989–90) [3]
Tylenol with codeine No. 3 100 tablets (McNeil) [acetaminophen with codeine]	$18.13	$5.58	325	103.9	12.0
Dilantin 100 mg, 100 capsules (Parke-Davis) [phenytoin]	13.55	4.10	322	42.2	18.8
Premarin 1.25 mg, 21 tablets (Wyeth-Ayerst) [conj. estrogens]	6.96	2.98	233	93.0	19.7
Ortho Novum 7/7/7—28 cycle (Ortho)	16.60	7.78	213	41.2	9.5
Lasix 40 mg, 100 tablets (Hoechst) [furosemide]	13.35	7.86	169	16.6	26.6
Feldene 10 mg, 100 tablets (Pfizer) [piroxicam]	99.25	61.16	162	48.1	15.2
Coumadin 2.5 mg, 100 tablets (Dupont) [warfarin sodium]	26.76	16.67	161	98.2	32.4
Zantac 150 mg, 60 tablets (Glaxo) [ranitidine]	73.63	48.91	151	39.3	14.4
Amoxil 250 mg, 100 capsules (Smith-Kline) [amoxicillin]	21.07	14.46	146	0	0
Indocin 50 mg, 30 capsules (Merck) [Indomethacin]	21.24	16.05	132	56.1	5.0

[1] Based on March 1989 U.S. price data, First Data Bank: Drug Information Data.
[2] Canadian prices are reported in U.S. dollars, based on March 1989 conversion rate. Canadian prices are the average of prices from the January 1989 versions of two provincial drug lists: Quebec's List of Medications and Ontario's Drug Benefit Formulary.
[3] U.S. price inflation based on price changes from December 12, 1985, to December 31, 1990, using prices from Medispan's Master Drug Data Base.

TABLE 3.—U.S. PRESCRIPTION DRUG PRODUCTS WITH HIGHEST RATES OF INFLATION 1985–90

Drug, manufacturer, use	Average annual percentage change in price 1985–90	Cumulative percent changes in price 1985–90	Average number of months between price changes
Premarin 0.625 mg tab (Wyeth-Ayerst) use: conjugated estrogen	21.5	131.0	8.5
Tylenol No. 3 (McNeil) tabs use: painkiller	16.1	128.5	8.4
Augmentin 250 mg tabs (Smith-Kline) use: antibiotic	16.3	112.6	5.5
Inderal 40 mg tabs (Wyeth-Ayerst) use: heart medication	17.1	112.4	8.9
Synthroid 50 mcg tabs (Flint) use: thyroid replacement	15.5	103.9	9.9
Lopressor 50 mg tabs (Ciba-Geigy) use: heart medication	13.7	102.9	8.5
Lanoxin 0.25 mg tabs (Burroughs-Wellcome) use: heart failure	15.6	95.8	11.9
Xanax 0.5 mg tabs (Upjohn) use: antianxiety	14.4	93.7	8.4
Tagamet 300 mg tabs (Smith-Kline) use: antiulcer	12.6	79.3	9.7
Proventil Inhaler (Schering-Plough) use: anti-asthma	11.8	74.1	9.1
Dilantin 100 mg caps (Parke-Davis) use: anti-epileptic	11.1	68.9	10.5
Tenormin 50 mg tab (ICI) use: heart medication	15.4	53.5	6.6
Prozac 20 mg caps (Eli Lilly) use: depression	12.9	27.1	10.6

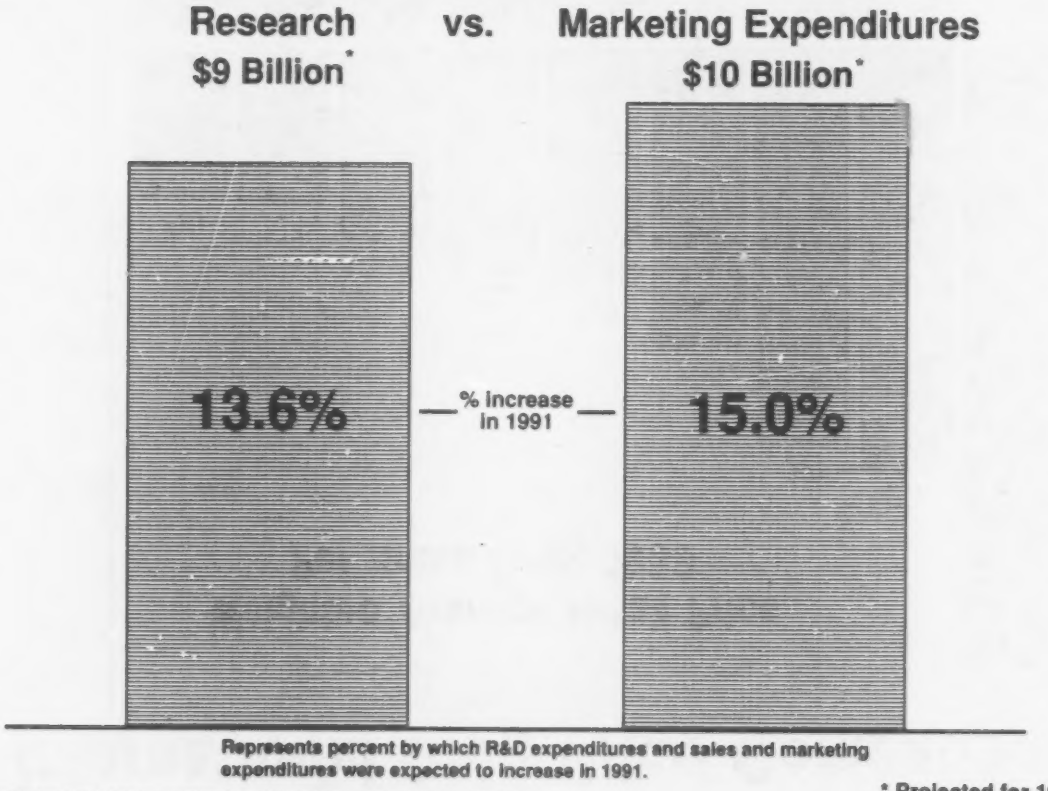
TABLE 4.—NEW MOLECULAR ENTITIES [NME's] APPROVED BY THE FOOD AND DRUG ADMINISTRATION [FDA] 1985–90

Manufacturer	Number approved by therapeutic category [1]		
	1–A	1–B	1–C
Abbott Laboratories [2]	0	1	2
Allergan, Inc [2]	0	1	1
American Cyanamid Co. (Lederle Laboratories [2])	0	0	1
American Home Products [2] (Ayerst Pharmaceuticals, Wyeth Pharmaceuticals)	0	0	1
Baxter International [2]	0	0	0
Bristol-Myers Squibb [2]	1	5	4
Burroughs-Wellcome	2	2	0
Ciba-Geigy	2	2	0
Dupont Pharmaceuticals	0	2	1
Flint Pharmaceuticals	0	0	0
Hoechst-Roussell	0	0	0
Johnson and Johnson [2] (Ortho Pharmaceuticals, McNeil Pharmaceuticals)	0	1	3
Glaxo	0	2	3
Hoffman La-Roche [2]	0	2	2
Lederle	0	0	1
Eli Lilly Company [2]	0	2	5
Marion Merrell Dow	1	1	0
Merck Sharp and Dohme [2]	1	4	3
Pfizer Pharmaceuticals [2]	1	0	3
Rorer Rhone Poulenc	0	1	1
Sandoz	2	0	1
Schering-Plough [2]	0	1	2
Smith-Kline Beecham [2]	0	1	1
Sterling Drug Co [2]	0	0	0
Syntex Laboratories [2]	1	0	4
Upjohn Co [2]	0	0	0
Warner-Lambert [2] (Parke-Davis)	0	0	0
Total approved (N.B. Columns do not add up to totals because not all manufacturers that had NME's approved during 1985–90 are reported here)	[3] 21	[4] 41	[5] 56

[1] Food and Drug Administration [FDA] therapeutic category ratings (for new molecular entities):
1–A = Important Therapeutic Gain over currently-marketed drugs.
1–B = Modest Therapeutic Gain over currently-marketed drugs.
1–C = Little or No Therapeutic Gain over currently-marketed drugs.
[2] Indicates that the company has a manufacturing operation in Puerto Rico.
[3] 18 percent.
[4] 35 percent.
[5] 47 percent.

Chart 9

Drug Manufacturers – 1991



Represents percent by which R&D expenditures and sales and marketing expenditures were expected to increase in 1991.

Source: Forbes Magazine, April 15, 1991, based on information provided by the Pharmaceutical Manufacturers Association

* Projected for 1991

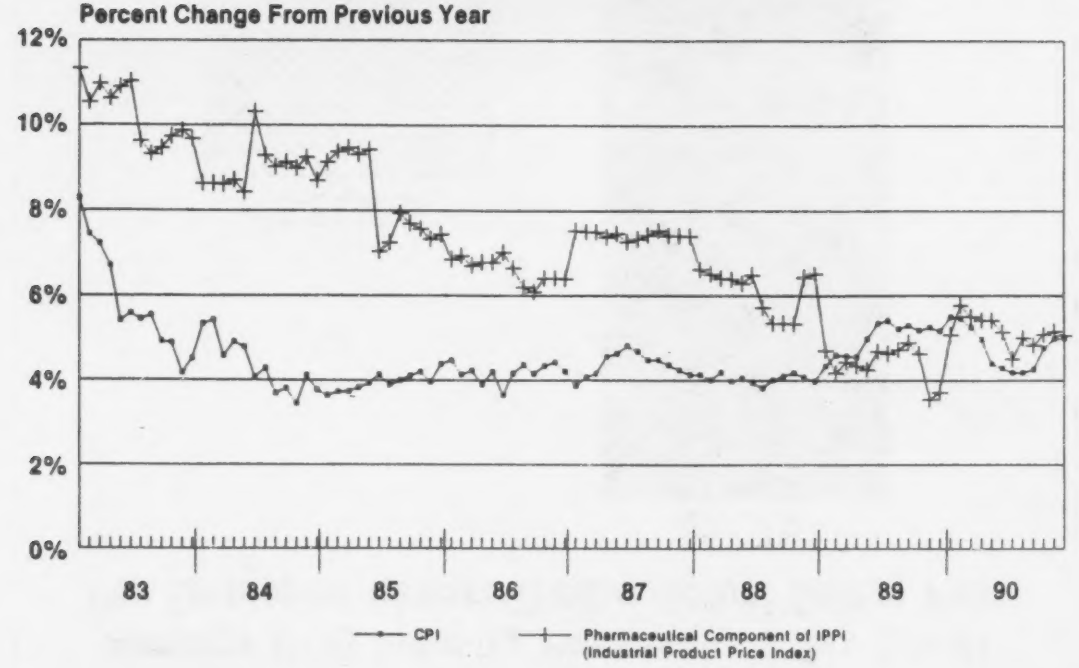
Chart 10

International Drug Price Comparison

Source: 'Indicatori Farmaceutici', annual survey of Farmindustria, the Italian pharmaceutical manufacturers association, published 1990

Chart 11

PERCENT YEAR TO YEAR CHANGE IN THE INDEX
VALUES FOR CPI AND PHARMACEUTICAL COMPONENT OF IPPI (BASE 1986 = 100)



Source: Statistics Canada

March 1991

Chart 12

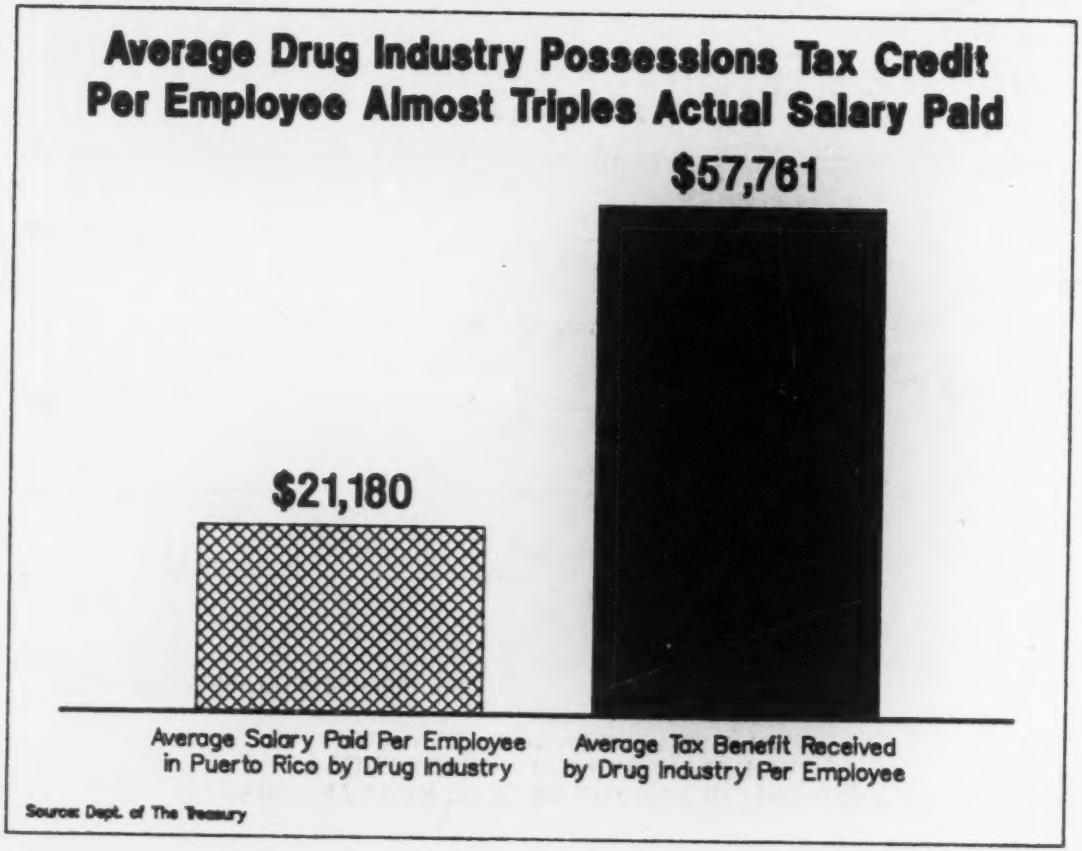
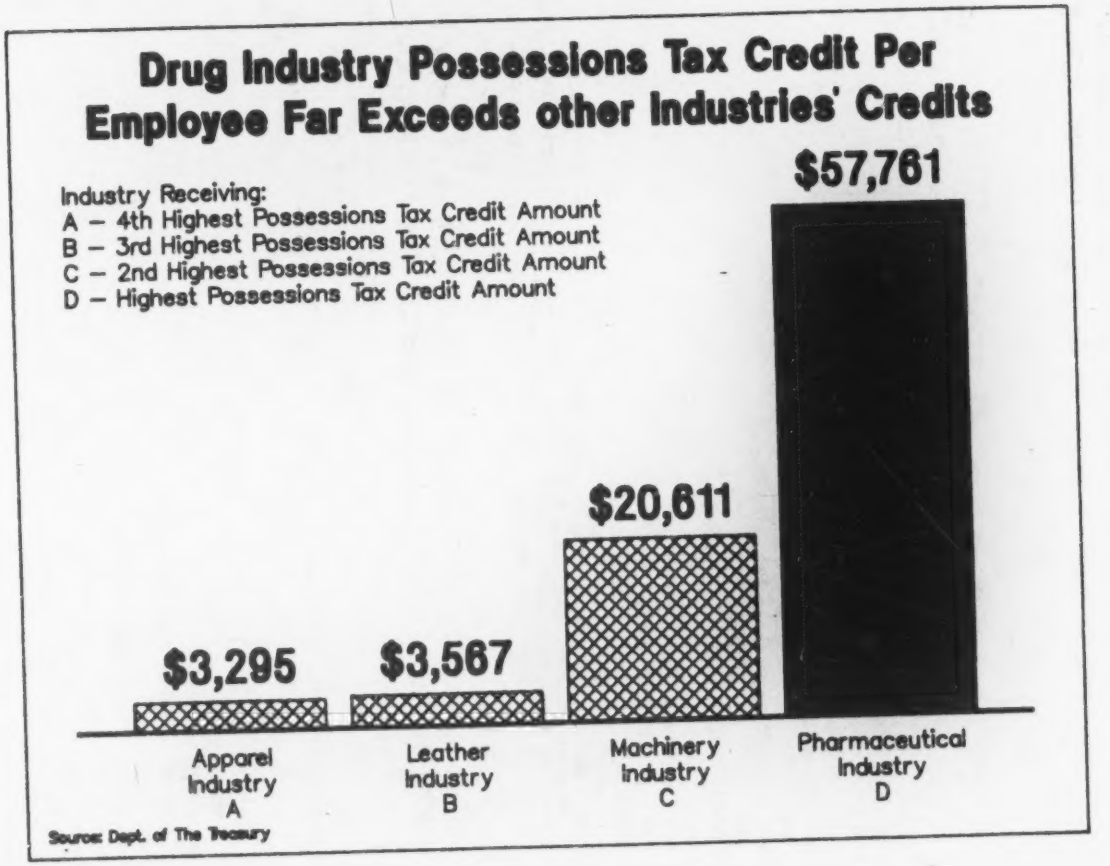

Average Drug Industry Possessions Tax Credit
Per Employee Almost Triples Actual Salary Paid
$57,761
$21,180
Average Salary Paid Per Employee
in Puerto Rico by Drug Industry
Average Tax Benefit Received
by Drug Industry Per Employee
Source: Dept. of The Treasury

Chart 13


Drug Industry Possessions Tax Credit Per Employee Far Exceeds other Industries' Credits
Industry Receiving:
A – 4th Highest Possessions Tax Credit Amount
B – 3rd Highest Possessions Tax Credit Amount
C – 2nd Highest Possessions Tax Credit Amount
D – Highest Possessions Tax Credit Amount
$3,295
$3,567
$20,611
$57,761
Apparel Industry A
Leather Industry B
Machinery Industry C
Pharmaceutical Industry D
Source: Dept. of The Treasury